UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Wednesday, March 29, 2017

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 66675-3
DP Barcode: D438334
Product Name: Magna-Bon Bahama Klear

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Jenny Tao, Senior Toxicologist
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To: Eric Miederhoff, PM 31/ Joseph Daniels
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Magna-Bon II, LLC

FORMULATION FROM LABEL:

PC Code	Active Ingredient(s):	% by wt.
024401	Copper sulfate pentahydrate	19.8
	Other Ingredient(s):	80.2
	Total:	100.00

I BACKGROUND: The registrant, Magna-Bon, LLC, has submitted an acute dermal toxicity study (MRID 50166102) and a primary skin irritation study (MRID 50166101) to amend the precautionary labeling of their registered product, *Magna-Bon Bahama Klear*, EPA Reg. No.: 66675-3. These two studies were conducted on EPA Reg. No. 66675-4, which contains the same concentration of the active ingredient. This subject product is for use on raw agricultural commodities.

In a previous 1/9/2009 PRB/SRRD (now PRD) review of 66675-3, the acute dermal toxicity and primary skin irritation studies were waived and assigned toxicity category I for both endpoints. For this submission, the registrant has submitted an acute dermal toxicity study and states that they want to remove the acute dermal toxicity category I labeling assigned to their product.

The 1/9/2009 review of 66675-3 states that both reg. Nos. 66675-3 and 61943-1 were placed in batch 4 of the Coppers RED. Because of this, CTT will be citing acute toxicity data from the 6/23/1989 RD/PRS review of 61943-R (-1). The acute inhalation toxicity study was previously cited from 66675-4.

II RECOMMENDATIONS:

1. The Chemistry and Toxicology Team (CTT) finds EPA Reg. No. 66675-3 and 66675-4 to be substantially similar to each other

2. The submitted acute dermal toxicity and primary skin irritation studies are both acceptable. CTT will use the results of these studies to replace the toxicity category I assignments for both of these endpoints. These will be merged with the other toxicity categories from the 1/9/2009 acute toxicity review.

The acute toxicity profile for File Symbol 66675-3 is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	41916101	III	Cited/61943-1
Acute Dermal Toxicity	50166102	IV	Acceptable
Acute Inhalation Toxicity	47520603	IV	Cited/66675-4
Primary Eye Irritation	None	I	Waived
Primary Skin Irritation	50166101	IV	Acceptable
Dermal Sensitization	41394801	Nonsensitizer	Acceptable

III LABELING:

Label Review System

PRODUCT ID #: 066675-00003

PRODUCT NAME: Magna-Bon Bahama Klear

PRECAUTIONARY STATEMENTS
SIGNAL WORD: DANGER

SPANISH SIGNAL WORD:
PELIGRO
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Child Resistant Packaging Required.

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Primary Eye Irritant toxicity. The following statements are suggested types of information that may be included, if applicable:
- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Label Created by: Ian Blackwell on 03/28/2017 Last Updated by: Ian Blackwell on 03/28/2017

This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that the Product Manager assign this product Restricted-Use classification; if not, the registrant should place this product in CRP.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 50166102 **Study Completion Date**: 12/18/2009
Lab Study No.: 28293

Testing Laboratory: Product Safety Laboratories
Author: S. Dana Oley, B.A.
Quality Assurance (40 CFR §160.12): Included

Test Material: Magna-Bon Pro-Teck, "clear, blue liquid"

Species: Sprague-Dawley albino rats
Weight: Males = 302-335 g **Age**: 9-10 weeks
Females = 215-243 g
Source: Ace Animals, Inc.

Summary:

1. **LD_{50} (mg/kg)**:

Males > 5,000 mg/kg
Females > 5,000 mg/kg
Combined > 5,000 mg/kg

2. **The estimated LD_{50} is greater than 5,000 mg/kg of body weight.**

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation from 870.1200): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000 mg/kg	0/5	0/5	0/10

Observations: Erythema at dose site, scab on back, mechanical damage due to patch removal, and, anogenital staining.

Gross Necropsy Findings: No gross abnormalities were observed.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 31 **Reviewer**: I. Blackwell
MRID No.: 50166101 **Study Completion Date**: 12/18/2009
Lab Study No.: 28295

Testing Laboratory: Product Safety Laboratories
Study Director: S. Dana Oley, B.A.

Quality Assurance (40 CFR §160.12): Included

Test Material: Magna-Bon Pro-Teck, "clear, blue liquid"
Dosage: 0.5 mL

Species: New Zealand albino rabbit
Weight: Not reported **Age**: Young adult
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations from 870.2500):

Results: One-hour after exposure to the test material, 3/3 test subjects displayed well-defined erythema, 2/3 slight edema and 1/3 very slight erythema. Twenty-four and forty-eight hours after exposure, 2/3 had well-defined erythema, 1/3 very slight erythema, and, 3/3 very slight edema. Seventy-two hours after exposure, 2/3 animals had very slight erythema.

The incidence and severity of irritation decreased over time, and all animals were free of dermal irritation by Day 7.

Special Comments: None.